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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/601,953	
	Filing Date	6/24/2003	
	First Named Inventor	Steven C. Quay	
	Art Unit	1614	
	Examiner Name		
Total Number of Pages in This Submission	19	Attorney Docket Number	02-03US

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to (TC)
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Nastech Pharmaceutical Company Inc.		
Signature			
Printed name	Peter J. Knudsen		
Date	November 21, 2005	Reg. No.	40682

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steven C. Quay

Attorney Docket No.: 02-03US

Serial No.: 10/601,953

Group Art Unit: 1614

Filed: 6/24/2003

Title: COMPOSITIONS AND METHODS  
FOR MODULATING PHYSIOLOGY  
OF EPITHELIAL JUNCTIONAL  
ADHESION MOLECULES FOR  
ENHANCED MUCOSAL  
DELIVERY OF THERAPEUTIC  
COMPOUNDS

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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

This Information Disclosure Statement is submitted:

- ☒ under 37 CFR 1.97(b), or  
(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- ☐ under 37 CFR 1.97(c) together with either a:  
☐ Statement under 37 CFR 1.97(e), or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with a:  
☐ Statement under 37 CFR 1.97(e), and  
☐ a \$180.00 fee set forth in 37 CFR 1.17(p).  
(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

☒ Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,

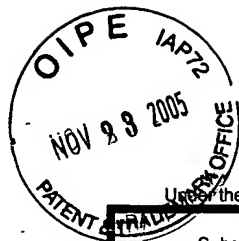


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Peter J. Knudsen  
Attorney/Agent for Applicant(s)  
Reg. No. 40682

Date: November 21, 2005

Telephone No.: 425-908-3643



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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/601,953	
			Filing Date	6/24/2003	
			First Named Inventor	Quay	
			Art Unit	1614	
			Examiner Name		
Sheet	1	of	15	Attorney Docket Number	02-03US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 5,554,388	Issued 09-10-1996	Danbiosyst UK Limited	
		US- 5,629,011	Issued 05-13-1997	Danbiosyst UK Limited	
		US- 5,744,166	Issued 04-28-1998	Danbiosyst UK Limited	
		US- 5,935,604	Issued 08-10-1999	Danbiosyst UK Limited	
		US- 6,048,536	Issued 04-11-2000	Medeva Holdings BV	
		US- 6,110,747	Issued 08-29-2000	Adherex Technologies, Inc.	
		US- 6,136,606	Issued 10-24-2000	Medeva Holdings BV	
		US- 6,228,396	Issued 05-08-2001	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,248,864	Issued 06-19-2001	Adherex Technologies, Inc.	
		US- 6,342,251	Issued 01-29-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,391,318	Issued 05-21-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre	
		US- 6,383,513	Issued 05-07-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 90/09780 (International Application Number PCT/GB90/00291)	09-07-1990	Danbiosyst UK Limited		
		WO 93/15737 (International Application Number PCT/GB93/00228)	08-19-1993	Danbiosyst UK Limited		
		WO 95/35100 (International Application Number PCT/GB95/01458)	12-28-1995	Danbiosyst UK Limited		
		WO 98/47535 (International Application Number PCT/GB98/01147)	10-29-1998	Danbiosyst UK Limited		
		WO 99/27905 (International Application Number PCT/GB98/03572)	06-10-1999	Danbiosyst UK Limited		
		WO 03/080021 (International Application Number PCT/GB03/01183)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

Examiner Signature		Date Considered	
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			Application Number	10/601,953	
			Filing Date	6/24/2003	
			First Named Inventor	Quay	
			Art Unit	1614	
			Examiner Name		
Sheet	2	of	15	Attorney Docket Number	02-03US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 6,387,917	Issued 05-14-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,432,440	Issued 08-13-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 03/080022 (International Application Number PCT/GB03/01184)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd.		
		WO 2004/062561 (International Application Number PCT/GB2004/000057)	07-29-2004	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

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				Application Number	10/601,953
				Filing Date	6/24/2003
				First Named Inventor	Quay
				Art Unit	1614
				Examiner Name	
Sheet	3	of	15	Attorney Docket Number	02-03US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ARMSTRONG et al, "Clinical Modulation of Oral Leukoplakia and Protease Activity by Bowman-Birk Inhibitor Concentrate in a Phase IIa Chemoprevention Trial," <i>Clinical Cancer Research</i> , December 2000, vol. 6 no. 12, pages 4684-4691.	
		TOMEE et al, "Secretory leukoprotease inhibitor: a native antimicrobial protein presenting a new therapeutic option?" <i>Thorax</i> , February 1998, vol. 53 no. 2, pages 114-116.	
		TOMEE et al, "Antileukoprotease: An Endogenous Protein in the Innate Mucosal Defense against Fungi," <i>The Journal of Infectious Diseases</i> , September 1997, vol. 176 no. 3, pages 740-747.	
		RAO et al, "Interaction of Secretory Leukocyte Protease Inhibitor with Proteinase-3," <i>American Journal of Respiratory Cell and Molecular Biology</i> , June 1993, vol. 8 no. 6, pages 612-616.	
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		FARRAJ et al, "Nasal Administration of Insulin Using Bioadhesive Microspheres as a Delivery System," <i>Journal of Controlled Release</i> , 1990, vol. 13, pages 253-261, Elsevier Science Publishers B.V., Amsterdam.	
		ILLUM et al, "Chitosan as a Novel Nasal Delivery System for Peptide Drugs," <i>Pharmaceutical Research</i> , 1994, vol. 11 no. 8, pages 1186-1189, Plenum Publishing Corporation.	
		COYNE et al, "Enhanced Epithelial Gene Transfer by Modulation of Tight Junctions with Sodium Caprate," <i>American Journal of Respiratory Cell and Molecular Biology</i> , November 2000, vol. 23, pages 602-609, High Wire Press.	
		FERRUZA et al, "Copper treatment alters the permeability of tight junctions in cultured human intestinal Caco-2 cells," <i>American Journal of Physiology</i> , December 1999, 277 (6 Pt 1): G1138-1148.	
		LIU et al, "Dodecylphosphocholine-Mediated Enhancement of Paracellular Permeability and Cytotoxicity in Caco-2 Cell Monolayers," <i>Journal of Pharmaceutical Sciences</i> , November 1999, vol. 88, no. 11, pages 1161-1168.	
		KARLSSON et al, "Paracellular drug transport across intestinal epithelia: influence of charge and induced water flux," <i>European Journal of Pharmaceutical Sciences</i> , October 1999, vol. 9, no. 1, pages 47-56.	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<i>Application Number</i>	10/601,953
		<i>Filing Date</i>	6/24/2003
		<i>First Named Inventor</i>	Quay
		<i>Art Unit</i>	1614
		<i>Examiner Name</i>	
(Use as many sheets as necessary)		<i>Attorney Docket Number</i>	02-03US
Sheet	4	of	15

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		DUIZER et al, "Absorption Enhancement, Structural Changes in Tight Junctions and Cytotoxicity Caused by Palmitoyl Carnitine in Caco-2 and IEC-18 Cells," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , October 1998, vol. 287, no. 1, pages 395-402.	
		BREWSTER et al, "The Effect of Dihydropyridine N-Substitution on the Brain-Targeting Efficacy of a Zidovudine Chemical Delivery System," <i>Pharmaceutical Research</i> , 1993, vol. 10, no. 9, pages 1356-1362.	
		DREJER et al, "Intranasal Administration of Insulin With Phospholipid as Absorption Enhancer: Pharmacokinetics in Normal Subjects," <i>Diabetic Medicine</i> , 1992, vol. 9, pages 335-340.	
		FISHER et al, "Effect of L- $\alpha$ -lysophosphatidylcholine on the nasal absorption of human growth hormone in three animal species," <i>International Journal of Pharmaceutics</i> , 1991, vol. 74, pages 147-156, Elsevier Science Publishers B.V.	
		HALMOS et al, "Synthesis of O-methylsulfonyl derivatives of D-glucose as potential alkylating agents for targeted drug delivery to the brain. Evaluation of their interaction with the human erythrocyte GLUT1 hexose transporter," <i>Carbohydrate Research</i> , 1997, vol. 299, pages 15-21, Elsevier.	
		HOCHMAN and ARTURSSON, "Mechanisms of absorption enhancement and tight junction regulation," <i>Journal of Controlled Release</i> , 1994, vol. 29, pages 253-267.	
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		NEGRI et al, "Glycodelphinolins: opioid peptides with potent and prolonged analgesic activity and enhanced blood-brain barrier penetration," <i>British Journal of Pharmacology</i> , 1998, vol. 124, pages 1516-1522, Stockton Press.	
		PARDRIDGE, "New approach to drug delivery through the blood-brain barrier," <i>Trends in Biotechnology</i> , 1994, vol. 12, pages 239-245, Elsevier Science Ltd., Cambridge, UK.	
		POLT et al, "Glycopeptide enkephalin analogues produce analgesia in mice: Evidence for penetration of the blood-brain barrier," <i>Proc. Natl. Acad. Sci. USA</i> , July 1994, vol. 91, pages 7114-7118, Pharmacology.	
		TAMAI et al, "Structure-Internalization Relationship for Adsorptive-Mediated Endocytosis of Basic Peptides at the Blood-Brain Barrier," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 1997, vol. 280, no. 1, pages 410-415.	

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			<i>Filing Date</i>	6/24/2003
			<i>First Named Inventor</i>	Quay
			<i>Art Unit</i>	1614
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(Use as many sheets as necessary)			<i>Attorney Docket Number</i>	02-03US
Sheet	5	of	15	

NON PATENT LITERATURE DOCUMENTS			
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		TSUZUKI et al, "Adamantane as a Brain-Directed Drug Carrier for Poorly Absorbed Drug. 2. AZT Derivatives Conjugated with the 1-Adamantane Moiety," <i>Journal of Pharmaceutical Sciences</i> , April 1994, vol. 83, no. 4, pages 481-484.	
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		THANOU et al, "Intestinal Absorption of Octreotide: N-Trimethyl Chitosan Chloride (TMC) Ameliorates the Permeability and Absorption Properties of the Somatostatin Analogue <i>In vitro</i> and <i>In vivo</i> ," <i>Journal of Pharmaceutical Sciences</i> , July 2000, vol. 89, no. 7, pages 951-957.	
		TAMAI and TSUJI, "Transporter-Mediated Permeation of Drugs Across the Blood-Brain Barrier," <i>Journal of Pharmaceutical Sciences</i> , November 2000, vol. 89, no. 11, pages 1371-1388.	
		ABBOTT, "Inflammatory Mediators and Modulation of Blood-Brain Barrier Permeability," <i>Cellular and Molecular Neurobiology</i> , April 2000, vol. 20, no. 2, pages 131-147, Plenum Publishing Corporation.	
		UCHIMAYA et al, "Enhanced Permeability of Insulin across the Rat Intestinal Membrane by Various Absorption Enhancers: Their Intestinal Mucosal Toxicity and Absorption-enhancing Mechanism of n-Lauryl-β-D-maltopyranoside," <i>J. Pharm. Pharmacol.</i> , November 1999, vol. 51, no. 11, pages 1241-1250.	
		LIU et al, "Structure-Activity Relationships for Enhancement of Paracellular Permeability by 2-Alkoxy-3-alkylamidopropylphosphocholines across Caco-2 Cell Monolayers," <i>Journal of Pharmaceutical Sciences</i> , November 1999, vol. 88, no. 11, pages 1169-1174.	
		FASANO, "Modulation of Intestinal Permeability: An Innovative Method of Oral Drug Delivery for the Treatment of Inherited and Acquired Human Diseases," <i>Molecular Genetics and Metabolism</i> , May 1998, vol. 64, pages 12-18, Academic Press.	
		FASANO and UZZAU, "Modulation of Intestinal Tight Junctions by Zonula Occludens Toxin Permits Enteral Administration of Insulin and Other Macromolecules in an Animal Model," <i>J. Clin. Invest.</i> , March 1997, vol. 99, no. 6, pages 1158-1164.	
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		LEWIS et al, "PMA alters folate receptor distribution in the plasma membrane and increases the rate of 5-methyltetrahydrofolate delivery in mature MA104 cells," <i>Biochimica et Biophysica Acta</i> , 1998, vol. 1401, pages 157-169.	
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